

# Quality control of parenterals

[Science](#), [Biology](#)



From Greek, Para outside; enter= intestine and exerts their action by directly entering into the systemic circulation. The quality of parenterals is the sum of all parameters that contribute to safety, efficacy and therapeutic efficacy of the drug. Drug products administered by injection are characterized by three qualities: pyrogenicity, and freedom from particulate matter. The USP compendia requirements has recommended the following tests for parenteral products:

- 1 . Pyrogen Testing.
- 2. Sterility Testing.
- 3. Particulate matter Testing.
- 4. Package integrity Test.
- 5. Safety Test.

**Pyrogen Testing** Pyrogens are fever producing substances, which are metabolic products of microorganisms. Chemically, they are lipid substances associated with a carrier molecule, which is usually a polysaccharide.

Pyrogens are produced by many microorganisms including bacteria, yeasts and molds. Most potent pyrogens are the endotoxins produced from the cell walls of the Gram- negative bacteria. Pyrogen can cause a lot of damage, if they are injected into a human being. Hence every batch of parenterals is tested for the presence of pyrogen. Page Number 5 Following Tests are Performed for Pyrogen testing: A. Rabbit Pyrogen Test (RPT) B. Limulus Amoebocyte Lysate (LAL) Test C. Monocyte Activation Test (MAT) A.

**Rabbit Pyrogen Test (RPT)** Introduction Selection of animals Animal quarters Retaining boxes Materials Thermometer Preliminary test Main test

Interpretation 0 Introduction It is an in vivo test to detect the presence of

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pyroxene in parental to ensure their quality standards. In 1942 it was added on USPS as official test but it was replaced with ALA test in 1982. Biologic are still tested with RPR Early indentation detection was accomplished by injecting rabbits with the sample and observing the response in their body temperature. Rabbits have similar indentation tolerance to humans, and were thus an ideal choice. However, this method was costly, time consuming, and prompted protests from animals rights advocates. But perhaps the biggest drawback of this test was its inability to quantify the indentation level.

Selection of animals Rabbits are used in this test because they show similar response as in humans. Following is selection criteria according to USPS

- 0 Albino rabbits should be used which grams in weight.
- 0 Rabbit should not loss its weight during week of test
- 0 Rabbit should be physically healthy
- 0 Rabbit should be on balance diet
- 0 Rabbit should not be administered with any anti body

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0 The rabbits which are used three days before in a negative pyroxene test are not used

- 0 The rabbits which are used two weeks before in a positive pyroxene test are not used

0 Animal quarters Rabbits should be kept in special cages and individual rabbit in a single cage.

Quarter and cage should be fulfilled following criteria:

- 0 Design of cage should be certified from ALL (American association of accreditation of laboratory animals)
- 0 Temperature of quarter should be 20 to 30 degree Celsius (temperature of performance area should also be in this range with deviation of 3)
- 0 If temperature of performance area is different from area where animals are kept then animals must be brought in performance area

18 hours before test 0 In performance area there should not be noise, due to noise temperature of rabbit can rise from 0. To 10 degree Celsius , which become normal after 6 to 9 hours. 0 Retaining boxes Rabbits are kept in separate boxes 1 hour before performance, design of boxes should be such that body can easily move and neck is at opening side. 0 Materials Materials such as syringes glassware etc. Should be washed with water for injection and place in hot air oven at 200 degree Celsius for 1 hour or at 250 degree Celsius for 30 minutes for dehydrogenation..

Treat all diluents and solutions for washing and rinsing of devices or parentally injection assemblies in a manner that will assure that they are sterile and pyroxene -free. Periodically perform control pyroxene tests on representative portions of the diluents and solutions for washing or rinsing of the apparatus. 7th - A I Survivors The University of Lahore Page Number 7 0 Thermometer theorists probes or similar probes that have been calibrated to assure an accuracy of  $\pm 0.1$  0 and have been tested to determine that a maximum reading is reached in less than 5 minutes. Rectal thermometer is used in this test which is calibrated with 1 degree Celsius marks.

Thermometer is inserted at depth of 5 centimeter. Temperature should be measured within 5 minutes. 0 Preliminary test Measure the temperature 1-1. 5 hours before test 0 Wash the marginal ear vein with ethyl alcohol (antiseptic) ethyl alcohol also act as clearing agent. 0 Now inject pyroxene free water with dose of 10 ml per keg. 0 Measure the temperature at intervals of 30 minutes for 3 hours 0 Any rabbit showing variation in temperature of 0. 6 degree will not be used in main tests. 0 Main test Select

three rabbits which are passed in the preliminary test. Monitor the temperature and inject the product after 90 minutes in marginal ear vein Dose should be 0. ml/kg to 10 ml/kg as specified in individual monogram Product can be eluted with pyroxene free water or any solvent recommended in official books Quantity of drug is as in monogram. 0 Measurement of temperature and pyroxene response Measure the initial temperatures within 40 minutes of injection for this purpose take one reading at after 10 minutes and second after 30 minutes average of both will be the initial temperature. 7th - A I Survivors The University of Lahore Page Number 8 Now monitor the temperature for 3 hours at the intervals of 30 minutes and note the highest temperature.